

PATENT
USSN 10/053,758
Docket 002980US; 018/183c

REMARKS

This paper is responsive to the Office Action dated January 25, 2005, which is the first action on the merits of the application.

Claims 1-17 and 20 were previously pending in the application; claims 1-8 were under examination. Upon entry of this Amendment, certain claims are reworded, claims 17-22 are canceled, and claims 23-26 are added. Claims 23 and 25 fall within the group under examination; whereas claims 24 and 26 fall into the same group as claims 9-16, which have been withdrawn from examination.

Accordingly, claims 1-16 and 23-26 are now pending in the application; claims 1-8, 23, and 25 are under examination. Claims 9-16, 24, and 26 are subject to a request for rejoinder pursuant to MPEP § 821.04.

Reconsideration and allowance of the application is respectfully requested.

Interview summary:

The undersigned is grateful for the telephone interviews conducted with the Examiner on May 6, 2005 and May 12, 2005. The relevance of the Harley Declaration to the current rejections under 35 USC § 103 were discussed, along with alternatives for addressing the double patenting rejection. The application is now believed to be in condition for allowance.

Claim Amendments:

The new claims are supported *inter alia* by the claims as previously presented, and by SEQ. ID NOs:225, and 67 as originally filed. The sequences are as follows:

- SEQ. ID NO:225: The protein sequence of full-length hTERT. (Figure 53)
- SEQ. ID NO:67: A portion of the hTERT protein sequence (Figure 27), contained within SEQ. ID NO:225.

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Where both a genus and a species or subgenus are disclosed in a specification, the case law permits the applicant to claim the genus with a negative limitation to the species or subgenus.

If alternative elements are *positively* recited in the specification, then they may be explicitly *excluded* in the claims: [The] specification, having described the whole, necessarily described the part remaining. *In re Johnson*, 194 USPQ 187, 196 (CCPA 1977). See also *Ex parti Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984).

Thus, no new matter is added to the application as a result of entering the new claims.

Priority:

The Office Action indicates that this application is entitled to a priority date of May 6, 1997. However, some of the subject matter disclosed in this application was disclosed in earlier applications to which this application claims priority under 35 USC § 120. For example, the structure and use of SEQ. ID NO:67 (a portion of the hTERT protein; claims 25 and 26) is disclosed in both USSN 08/844,419 (filed April 18, 1997) and USSN 08/846,017 (filed April 25, 1997).

Rejections under 35 USC § 103:

Claim 1 stands rejected under § 103(a) as being obvious over U.S. Patent No. 5,583,016 ("Mammalian Telomerase", Villeponteau et al.), in view of Johnstone and Thorpe, which is an excerpt from a general reference on immunochemical techniques. Claims 1-8 also stand rejected under § 103(a) as being obvious over the '016 patent, in view of various combinations of Johnstone and Thorpe, U.S. Patent No. 5,001,225 (relied on by the Office with respect to making Fab and F(ab')₂ fragments of an antibody); U.S. Patent 4,816,567 (recombinant immunoglobulins); Huston et al., Proc. Natl. Acad. Sci. USA 85:5879-83, 1988 (Fv binding fragments); and WO 82/01461 (general use of antibody in immunoassays).

Applicants respectfully disagree. U.S. Patent No. 5,583,016 provides the sequence for the RNA component of human telomerase, which (along with hTERT) is part of the functional telomerase holoenzyme complex. The '016 patent refers to a method in which oligonucleotides complementary to the RNA component are used as affinity reagents for enriching telomerase holoenzyme from a biological mixture. This patent was filed on October 27, 1994.

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Subsequent work led to development of four and six-step purification protocols, in which affinity capture of hTERT by RNA component oligonucleotides is enhanced by prior enrichment. This was the subject of U.S. Patent No. 5,968,506 (Weinrich et al., "Purified Telomerase"), and related Patent Nos. 6,261,556, 6,517,834; 6,545,133; and 6,787,133. This series has a later priority date of August 4, 1995.

The '834 patent was addressed in the 37 CFR § 1.132 Declaration by Dr. Calvin Harley, filed in the present application on September 21, 2004. Dr. Harley stated that despite the importance of Dr. Weinrich's invention for use in drug screening, hTERT was still a minor component in the 3,550 fold enriched preparation of the '834 patent (in terms of total protein content). Dr. Harley explains that the proportion of hTERT in the preparation was too low to generate a specific polyclonal antibody, or to test the specificity of hybridoma clones.

Since the '834 patent does not provide hTERT sufficiently purified to make hTERT-specific antibody, it follows that the earlier technology of the '016 patent also does not provide hTERT sufficiently purified to make hTERT-specific antibody. Accordingly, the '016 patent does not place in the hands of the public the isolated monoclonal or recombinant antibodies claimed here.

The other references cited in the Office Action relating to general immunochemical techniques do not suggest how to modify the '016 Patent make a more purified preparation of hTERT, and so do not overcome the limitations discussed in the Harley Declaration.

Withdrawal of this rejection is respectfully requested.

Double patenting:

Claims 1 and 2 of this application stand rejected for statutory double patenting over claim 50 of USSN 09/721,477. Claims 1-8 stand rejected for obviousness-type double patenting over claims 50, 71, and 73 of the same application.

However, claims 50, 71, and 73 have been withdrawn from consideration in USSN 09/721,477, and are not under examination. Withdrawal of this rejection is requested.

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Request for Rejoinder:

Claims 9-16, 24, and 26 are method claims that incorporate limitations of the product claims under examination. Applicant hereby requests that these claims be rejoined, upon determination that the product claims are patentable, in accordance with MPEP § 821.04.

Claims covering the making of the antibody product by immunization (claims 17 and 20) have been cancelled.

Related applications:

Under 37 CFR § 1.56, applicants wish to remind the attention of the Examiner the other issued and pending application relating to sequences for telomerase reverse transcriptase.

- Issued patents for hTRT include U.S. 6,475,789; U.S. 6,261,836; U.S. 6,617,110; and U.S. 6,808,880.
- Allowed applications for hTRT include USSN 09/438,486; 09/843,676; and 10/054,295.
- The other pending applications for hTRT include USSN 08/974,584; 09/432,503; 09/721,477; 09/721,506; 10/053,758; 10/054,611; 10/044,692; 10/877,022; 10/877,124; 10/044,539, and 10/877,146.
- Patents claiming TRT from single cell ciliates include U.S. 6,093,809; U.S. 6,166,178; and U.S. 6,309,867.
- Patents and patent applications for mouse TRT include U.S. 6,767,719 and USSN 10/862,698.
- Patents and applications for the hTRT promoter include U.S. 6,610,839; U.S. 6,777,203; USSN 10/325,810; and USSN 10/674,836.
- Patents and applications for hTRT variants include U.S. 6,337,200 and USSN 09/990,080.
- Patents and applications for hTRT antisense oligonucleotides include U.S. 6,444,650; U.S. 6,627,619; and USSN 10/637,443.

The undersigned is not aware of any double patenting issue not previously raised or prosecution issue that should affect the patentability of the claims in this application. However, the Examiner should do her own assessment.

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Request for Interview

Applicants respectfully request that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

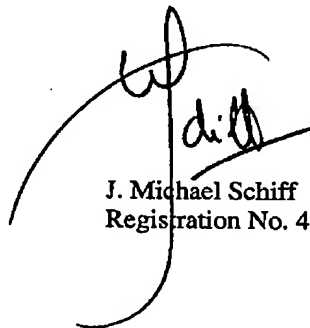
In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests an interview by telephone.

Fees Due

Enclosed with this Amendment is authorization to charge the Deposit Account for the extension of time.

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. Michael Schiff", is written over a large, stylized circular flourish.

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